The New Hampshire Department of Health and Human Services
Committee for the Protection of Human Subjects

Expedited Review Submission Checklist

Study Title:_____CPHS#_____
Primary Investigator:_____

The CPHS requires the following materials to be submitted for an Expedited Review (see the web page for details on Expedited Review criteria):

For Expedited Review / Work Preparatory to Research / Research with PHI Only:

___ A copy of either the Expedited Review Study Form (a.k.a summary protocol) (Dartmouth Investigators may use The Dartmouth CPHS Medical Record/Chart Review Form)

___ A copy of any grant application or protocol for the same study submitted to the U. S. Department of Health and Human Services or FDA, if applicable;

___ A copy of the investigator brochure(s), if applicable;

___ A copy of the consent form or waiver of consent;

___Letters of support from all sites under jurisdiction of the NH CPHS;

___Copies of written materials used in the study and to which subjects might be exposed, such as assessment tools that are not standard, scripts, treatment manuals that are not standard, advertisements; web based postings, or handouts.

For Continuing Reviews (that meet Expedited Review criteria based on study status):

- The project did not start and is no longer in operation.
  - ___ Completed, signed and dated Continuing Review form
  - ___ In the progress report section of the Continuing Review form, describe the circumstances leading to this project not starting.
  - ___ Copy of Summary Protocol in CPHS format

- The project did not start but is expected to start during the next year.
  - ___ Completed, signed and dated Continuing Review form
  - ___ In the progress report section of the Continuing Review form, describe the circumstances leading to this project not starting or being delayed.
  - ___A Human Subject Review Form (for studies that do not qualify for expedited review);
  - ___ A CPHS stamped copy of the consent (the one about to expire);
  - ___ A clean copy of the consent form;
  - ___ The sponsor protocol or NIH grant application (if applicable); and
  - ___ A copy of the Summary protocol.

- The project is ongoing.
  - ___ Completed, signed and dated Continuing Review form
  - ___ In the progress report section of the Continuing Review form, provide enough detail for the Committee to understand the current status of the project
  - ___ A Human Subject Review Form (for studies that do not qualify for expedited review);
  - ___ A CPHS stamped copy of the consent (the one about to expire);
  - ___ A clean copy of the consent form;

___ The sponsor protocol or NIH grant application (if applicable); and
___ A copy of the Summary protocol.
___ DSMB Summary (if applicable)

- The project is ongoing but closed to enrollment.
  ___ Completed, signed and dated Continuing Review form
  ___ In the progress report section of the Continuing Review form, provide enough detail for the Committee to understand the current status of the project
  ___ A Human Subject Review Form (for studies that do not qualify for expedited review)
  ___ The sponsor protocol or NIH grant application (if applicable),
  ___ A copy of the Summary protocol.
  ___ DSMB Summary (if applicable)
- The project concluded during the past year.
  ___ Completed, signed and dated Continuing Review form specifying the date the study ended
  ___ A Human Subject Review Form (for studies that do not qualify for expedited review);
  ___ A summary of the results;
  ___ The sponsor protocol or NIH grant application (if applicable); and
  ___ A copy of the Summary protocol.
  ___ DSMB Summary (if applicable)